UNITED STATES DISTRICT COURT
FOR THE
WESTERN DISTRICT OF NEW YORK

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| ATHENEX PHARMA SOLUTIONS, LLC, and ATHENEX PHARMACEUTICAL DIVISION, LLC, | ) | |
| Plaintiffs, | ) | |
| v. | ) | Case No. 1:18-cv-896 |
| PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC, | ) | |
| Defendants. | ) | |

**ORDER ON MOTION TO DISMISS**
**(Doc. 10)**

Plaintiffs Athenex Pharma Solutions, LLC ("Athenex Pharma") and Athenex Pharmaceutical Division, LLC ("APD") (collectively "Athenex") have filed this declaratory judgment action against Defendants Par Pharmaceutical, Inc. ("Par Pharmaceutical"), Par Sterile Products, LLC ("Par Sterile"), and Endo Par Innovation Company ("Endo") (collectively "Par"). Both Athenex and Par are pharmaceutical companies. Athenex seeks a declaration of non-infringement and invalidity of certain pharmaceutical patents owned by Par.

Par has moved to dismiss the complaint under Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction, arguing that Athenex has failed to allege a justiciable controversy under the Declaratory Judgment Act. Athenex has filed an opposition (Doc. 16), and Par has filed a reply (Doc. 19). Par subsequently filed a motion for leave to file supplemental information (Doc. 20), which the court granted on May 7, 2019 (Doc. 23). For the reasons stated below, the court GRANTS Par's motion to dismiss.

## Background

### I. Legal Background

The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. §§ 301–397, regulates drug manufacturing, marketing, and distribution. Section 355(a) of the FFDCA provides that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug" without the U.S. Food and Drug Administration's ("FDA") approval. Generally, a pharmaceutical company seeking to produce a new drug must file a New Drug Application ("NDA") for FDA approval. 21 U.S.C. § 355(a). Under the Drug Price Competition and Patent Term Restoration Act of 1984—Pub. L. No. 98–417, 98 Stat. 1585 (1984), *codified at* 21 U.S.C. §§ 355, 360cc, and 35 U.S.C. §§ 156, 271 (the "Hatch-Waxman amendments" to the FFDCA)—a pharmaceutical company seeking to produce a generic drug may submit an Abbreviated New Drug Application ("ANDA") for FDA approval. 21 U.S.C. § 355(j). Any patents claiming an approved drug are listed in the FDA's Approved Drug Products With Therapeutic Equivalence Evaluations, commonly known as the "Orange Book." *See Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002).

In 2013, Congress passed the Drug Quality and Security Act, which, among other things, added Section 503B to the FFDCA. *See* 113 Pub. L. No. 54, 127 Stat. 587 (2013), *codified at* 21 U.S.C. § 353b. Section 503B regulates drug products compounded by an "outsourcing facility." Drug compounding is defined as "the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug." 21 U.S.C. § 353b(d)(1).[1] An "outsourcing facility" is "a facility at one geographic location or address

[1] "Bulk drug substance . . . means the same as 'active pharmaceutical ingredient'. . . ." 21 C.F.R. § 207.3. "Active pharmaceutical ingredient means any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or

that—(i) is engaged in the compounding of sterile drugs; (ii) has elected to register as an outsourcing facility; and (iii) complies with all of the requirements of [§ 503B]." 21 U.S.C. § 353b(d)(4)(A). Under certain conditions, drugs compounded by a registered outsourcing facility are exempt from certain FDA drug approval requirements, including the procedures described in the Hatch-Waxman amendments. *See* 21 U.S.C. § 353b(a)–(b), (d)(4)(A). One condition is that the outsourcing facility may only compound products using bulk drug substances included on either (1) "a list established by the [FDA] identifying bulk drug substances for which there is a clinical need" (the "bulks list"); or (2) the FDA's drug shortage list. 21 U.S.C. § 353b(a)(2). Another condition is that the compounded drug cannot be "essentially a copy" of a drug approved by the FDA. 21 U.S.C. § 353b(a)(5).

The FDA is currently developing the bulks list. *See Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, 84 Fed. Reg. 4696 (Mar. 21, 2019) (to be codified at 21 C.F.R. § 216). In the meantime, the FDA has issued an industry guidance document that describes interim regulatory policies for outsourcing facilities that compound drugs using bulk drug substances. U.S. Dep't of Health & Human Servs. et al., *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry* (2017) (originally published in June 2016), *available at* https://www.fda.gov/media/94402/download [hereinafter *Interim Policy*]. The *Interim Policy* states that the FDA "does not intend to take action against an outsourcing facility for compounding a drug using a bulk drug substance that does not appear on the 503B bulks list" if, among other conditions, the substance appears on a

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other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body." 21 C.F.R. § 207.1.

list of "Category 1" substances that are currently under evaluation. *Id.* at 8. This policy no longer applies "[o]nce FDA has published in the Federal Register its decision not to place a particular substance on the 503B bulks list, the policy described in section III of this guidance no longer applies." *Id.* at 7.

## II. Facts

The following is drawn from Athenex's complaint (Doc. 1) and the exhibits attached to Par's motion for leave to file supplemental information (Doc. 20).

Par Sterile holds a New Drug Application ("NDA") for the drug Vasostrict. Par Pharmaceutical owns six patents listed in the Orange Book that cover Vasostrict, including U.S. Patent 9,375,478 (the "478 patent"); 9,678,526 (the "526 patent"); 9,744,209 (the "209 patent"); 9,744,239 (the "239 patent"); 9,750,785 (the "785 patent"); and 9,937,223 (the "223 patent") (collectively the "patents-in-suit"). The patents-in-suit are directed to methods for administering vasopressin, the active ingredient in Vasostrict, and are entitled "Vasopressin Formulations for Use in Treatment of Hypotension." Endo exclusively licenses the patents-in-suit.

Athenex Pharma is an outsourcing facility registered with the FDA under Section 503B of the FFDCA. It makes compounded drug products for hospitals and other health care providers. (Doc. 1 ¶ 22.) APD is a biopharmaceutical company that develops and markets the pharmaceuticals manufactured by Athenex Pharma. (*Id.*)

Athenex manufactures and markets compounded vasopressin products. On August 13, 2018, Athenex filed this declaratory judgment action against Par, seeking a declaration that Athenex did not infringe the patents-in-suit and that the patents-in-suit are invalid. Athenex began marketing compounded vasopressin products the same day it filed the complaint. (Doc. 16 at 26.)

At the time the complaint was filed, Vasopressin was listed as a Category 1 substance. FDA, *Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act* 3 (2018), *available at* https://www.fda.gov/media/94164/download. On March 4, 2019, the FDA published a decision stating that vasopressin will not be included on the bulks list. *List of Bulk Drug Substances for Which There Is a Clinical Need Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, 84 Fed. Reg. 7383 (2019).

In the complaint, Athenex alleges that an immediate and real controversy exists between the parties because "Par has launched a campaign to keep compounded vasopressin products from being on the market." (Doc. 1 ¶ 32.) To support this allegation, Athenex relies most heavily on three lawsuits initiated by Par against other parties. In October 2017, Par sued the FDA, seeking to enjoin an FDA policy that authorized the bulk compounding of vasopressin. (Doc. 1 ¶ 33 (citing *Par Sterile Prods., LLC v. Hargan*, 1:17-cv-02221 (D.D.C.)).) In that case, Par alleged that the FDA has violated the FDCA and the APA by authorizing "the large-scale production of unapproved vasopressin that will be administered to patients in a form that is essentially a copy of Vasostrict®." (Doc. 17-11 ¶ 11.) Par further alleged that "certain uses of vasopressin are covered by Par's five unexpired patents listed in FDA's Orange Book," and therefore "anyone seeking [the] FDA's approval to market such a follow-on version of Vasostrict® must comply with the patent-protection provisions of the FDCA applicable to follow-on drug products introduced by the Hatch-Waxman amendments." (*Id.* ¶ 12.)

Athenex alleges that Par's position in the FDA lawsuit is that "compounded vasopressin products are essentially copies of Vasostrict®" and therefore infringe the patents-in-suit. (Doc. 1

¶ 39.) According to Athenex, Par's position shows that "Par will bring patent infringement suits against the manufacturers and/or marketers of [] compounded vasopressin products." (*Id.*)

Par has also filed two lawsuits against prospective manufacturers of vasopressin products. In August 2017, Par Pharmaceutical and Par Sterile sued QuVa Pharma, Inc. ("QuVa") for misappropriation of trade secrets. Athenex alleges that QuVa plans to market a compounded vasopressin product. QuVa has filed counterclaims seeking a declaratory judgment that its products do not infringe the 478 patent, the 526 patent, the 209 patent, the 239 patent, and the 785 patent. In May 2018, Par sued Eagle Pharmaceuticals, Inc. ("Eagle") for infringement of the patents-in-suit after Eagle filed an ANDA seeking FDA approval to market a generic version of Vasostrict.

Athenex also alleges that Endo publicly stated in May 2018 that "Endo opposes the unapproved, bulk compounding of vasopressin, and will vigorously defend and protect its substantial investment in its proprietary products." (Doc. 1 ¶ 36.) Athenex alleges that Endo also referred to Par's lawsuits against the FDA and QuVa in a form filed with the United States Securities and Exchange Commission, stating "[w]e will continue to vigorously defend or prosecute the foregoing matters as appropriate, to protect our intellectual property rights, to pursue all available legal and regulatory avenues and to explore other options as appropriate in our best interests." (*Id.* ¶ 38.)

According to Athenex, "Par's pattern of actions creates a reasonable apprehension and substantial likelihood that Par will sue Athenex for the alleged infringement of the patents-in-suit, in an attempt to disrupt Athenex's plans to market its compounded vasopressin drug products." (*Id.* ¶ 42.)

## Standard of Review

"A case is properly dismissed for lack of subject matter jurisdiction under Rule 12(b)(1) when the district court lacks the statutory or constitutional power to adjudicate it." *Eliahu v. Jewish Agency for Israel*, 919 F.3d 709, 712 (2d Cir. 2019) (per curiam) (quoting *Makarova v. United States*, 201 F.3d 110, 113 (2d Cir. 2000)). The court must "accept the complaint's material allegations as true" and must "draw all reasonable inferences in the plaintiffs' favor." *Raymond Loubier Irrevocable Tr. v. Loubier*, 858 F.3d 719, 725 (2d Cir. 2017). The court may consider extrinsic evidence proffered by the parties. *Id.* Generally, "the plaintiff has the burden of proving by a preponderance of the evidence that subject matter jurisdiction exists." *Katz v. Donna Karan Co.*, 872 F.3d 114, 120 (2d Cir. 2017).

## Analysis

The Declaratory Judgment Act provides that: "In a case of actual controversy within its jurisdiction, . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). Because the Declaratory Judgment Act does not provide an independent basis for subject matter jurisdiction, a court's declaratory judgment jurisdiction is limited by the justiciability of "cases" or "controversies" under Article III of the Constitution. *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1335 (Fed. Cir. 2008). Thus, a district court has jurisdiction over a declaratory judgment action only if the suit meets Article III's case-or-controversy requirement. *Id.*

"The burden is on the party claiming declaratory judgment jurisdiction"—here, Athenex—"to establish that an Article III case or controversy existed at the time that the claim

for declaratory relief was filed and that it has continued since." *Danisco U.S. Inc. v. Novozymes A/S*, 744 F.3d 1325, 1329 (Fed. Cir. 2014). Carrying that burden "requires a showing of injury-in-fact, connection between the challenged conduct and the injury, and redressability by the requested remedy." *AIDS Healthcare Found., Inc. v. Gilead Scis., Inc.*, 890 F.3d 986, 990–91 (Fed. Cir. 2018) (citing *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 103–04 (1998)), *cert. denied*, 139 S. Ct. 415 (2018). While there is no bright-line test for determining whether an actual controversy exists in a declaratory judgment action, the basic standard is whether "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007) (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)). The court's analysis under this standard "must be calibrated to the particular facts of each case." *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 879 (Fed. Cir. 2008).

Following *MedImmune*, the Federal Circuit[2] has noted that "Article III does not mandate that the declaratory judgment defendant have threatened litigation or otherwise taken action to enforce its rights before a justiciable controversy can arise." *Danisco*, 744 F.3d at 1330 (citing *MedImmune*). However, the Federal Circuit has also reaffirmed "the bedrock rule that a case or controversy must be based on a *real* and *immediate* injury or threat of future injury that is *caused by the defendants*—an objective standard that cannot be met by a purely subjective or speculative fear of future harm." *Prasco*, 537 F.3d at 1339; *accord Asia Vital Components Co. v. Asetek*

[2] "Whether an actual case or controversy exists so that a district court may entertain an action for a declaratory judgment of non-infringement and/or invalidity is governed by Federal Circuit law." *3M Co. v. Avery Dennison Corp.*, 673 F.3d 1372, 1377 (Fed. Cir. 2012) (quoting *MedImmune, Inc. v. Centocor, Inc.*, 409 F.3d 1376, 1378 (Fed. Cir. 2005), *overruled on other grounds by MedImmune*, 549 U.S. 118).

*Danmark A/S*, 837 F.3d 1249, 1253 (Fed. Cir. 2016). Accordingly, "jurisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without some affirmative act by the patentee." *Asia Vital Components Co.*, 837 F.3d at 1253 (quoting *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1381 (Fed. Cir. 2007)). Rather, a declaratory judgment plaintiff must allege "conduct that can be reasonably inferred as demonstrating intent to enforce a patent." *Id.* (quoting *Hewlett–Packard Co. v. Acceleron LLC*, 587 F.3d 1358, 1363 (Fed. Cir. 2009)).

Here, Athenex does not allege that Par sought to enforce the patents-in-suit against Athenex or knew about Athenex's compounded vasopressin products before the complaint was filed. Rather, Athenex alleges that "Par has launched a campaign to keep compounded vasopressin products from being on the market" that gives rise to a real and immediate controversy between the parties. (Doc. 1 ¶ 32.) In particular, Athenex contends that the following factors, taken together, demonstrate Par's intent to enforce its patents against Athenex: (1) Par's litigation history; (2) Par's assertions that compounded vasopressin products are copies of Vasostrict; and (3) Par's public statements that it opposes compounded vasopressin products and plans to defend its rights. (*See Id.* ¶¶ 32–41.) According to Athenex, "Par's pattern of actions creates a reasonable apprehension and substantial likelihood that Par will sue Athenex for the alleged infringement of the patents-in-suit." (*Id.* ¶ 42.)

Par contends that the fact that it did not know about Athenex's compounded vasopressin products before the complaint was filed is "dispositive of the issue of subject matter jurisdiction." (Doc. 10-7 at 11 (citing *True Sci. Holdings, LLC v. Mars, Inc.*, No. 2:14CV193DAK, 2015 WL 574560, at *6 (D. Utah Feb. 11, 2015)). The court disagrees.

The Federal Circuit has noted that an actual controversy may exist "even when a patentee first learns of plaintiff's conduct upon receipt of the complaint." *Asia Vital Components Co.*, 837 F.3d at 1254 (quoting *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988)). The question of jurisdiction in this case does not turn on whether Par knew about the specific compounded vasopressin products manufactured by Athenex or specifically alleged that Athenex had infringed the patents-in-suit. *See id.* Instead, the relevant question is whether, under all the circumstances, Par's actions "can be reasonably inferred as demonstrating intent to enforce" the patents-in suit against Athenex. *Id.* (quoting *Hewlett–Packard*, 587 F.3d at 1363).

Considering the totality of the circumstances, Athenex has failed to demonstrate that an Article III case or controversy existed at the time it filed the complaint. A justiciable controversy generally does not exist without "an act directed toward [the plaintiff]." *Innovative Therapies, Inc.*, 599 F.3d at 1382; *accord Mama Cares Found. v. Nutriset Société Par Actions Cimplifiée*, 825 F. Supp. 2d 178, 183 (D.D.C. 2011) ("[A] patentee's actions toward third parties are generally not sufficient to establish declaratory judgment jurisdiction." (citing *Innovative Therapies*)). Here, it is undisputed that Par did not direct any actions towards Athenex before the complaint was filed. There is no indication that Par ever communicated with Athenex, either directly or indirectly. "While direct communication between a patentee and a declaratory plaintiff is not necessary" to establish an actual controversy, *Arris Grp., Inc. v. British Telecommunications PLC*, 639 F.3d 1368, 1378 (Fed. Cir. 2011), Athenex fails to allege any contact whatsoever between the parties prior to this litigation.

Athenex argues that Par lawsuits against QuVa, Eagle, and the FDA demonstrate its "willingness to sue to protect its product by whatever claims and causes of action are available." (Doc. 16 at 16.) "Prior litigation is a circumstance to be considered in assessing the totality of

circumstances . . . ." *Innovative Therapies, Inc. v. Kinetic Concepts, Inc.*, 599 F.3d 1377, 1382 (Fed. Cir. 2010). But the fact that a patentee has filed lawsuits "against other parties for other products does not, in the absence of any act directed toward [the plaintiff], meet the minimum standard discussed in *MedImmune*." *Id.*; *see also Organic Seed Growers & Trade Ass'n v. Monsanto Co.*, 851 F. Supp. 2d 544, 552 (S.D.N.Y. 2012) (noting that suits against third parties may be relevant "only if those suits are sufficiently similar to the one the patentee may potentially bring against the declaratory judgment plaintiffs"), *aff'd*, 718 F.3d 1350 (Fed. Cir. 2013).

Here, none of the three lawsuits are substantially similar to the suit Par may potentially bring against Athenex. Par's suit against the FDA challenges the FDA's Interim Policy under the Administrative Procedure Act; its rights under the patents-in-suit are not at issue. Par has sued QuVa for misappropriation of trade secrets, not patent infringement. Par's patent infringement suit against Eagle involves a generic vasopressin product, which is governed by the Hatch-Waxman framework—not a compounded vasopressin product, which was exempt from the Hatch-Waxman requirements at the time the complaint was filed. And because Athenex was not a party to any of the three lawsuits, these prior suits are not relevant to whether there is a case or controversy between Par and Athenex. *See Prasco*, 537 F.3d at 1341 n.10; *accord D2L Ltd. v. Blackboard, Inc.*, 671 F. Supp. 2d 768, 777 (D. Md. 2009); *cf. Danisco U.S. Inc.*, 744 F.3d at 1331 ("[A] history of patent litigation *between the same parties* involving related technologies, products, and patents . . . may weigh in favor of the existence of subject matter jurisdiction." (emphasis added)). Thus, Par's litigation history, when viewed under the totality of the circumstances in this case, is insufficient to create an actual controversy between the parties.

According to Athenex, "the purpose of Par's suit against [the] FDA is to enact regulatory change in order to block 503B compounders . . . from marketing compounded vasopressin products." (Doc. 16 at 20–21.) Athenex argues that such an "attempted regulatory change is one way for a declaratory judgment plaintiff to show injury." (*Id.* at 21.) The court does not find this argument persuasive. It is true that a patentee may cause an imminent risk of injury by "creating a barrier to the regulatory approval of a product that is necessary for marketing," *Prasco*, 537 F.3d at 1339 (citing *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1292–94 (Fed. Cir. 2008)), specifically in the context of the Hatch-Waxman framework. *See Caraco Pharm. Labs., Ltd.*, 527 F.3d at 1291–94. But because compounded vasopressin products were exempt from the Hatch-Waxman framework at the time the complaint was filed, Athenex did not need FDA approval to begin marketing its product. Par's lawsuit against the FDA merely claims that compounded vasopressin products should be subject to FDA approval under the Hatch-Waxman framework. Par cannot create a barrier to FDA approval of compounded vasopressin products just by asserting that such a barrier should exist.

Athenex further contends that Par asserted in its complaint against the FDA, as well as other court filings, "that all compounded versions of vasopressin infringe [the patents-in-suit] because they are either copies of, nearly identical to, or follow-on products of, Vasostrict®." (Doc. 16 at 15.) These assertions do not demonstrate an imminent threat of patent enforcement against Athenex. The Federal Circuit has held that an actual controversy may arise "where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party." *SanDisk Corp.*, 480 F.3d at 1381. Putting aside the fact that the patents-in-suit are not at issue in Par's lawsuit against the FDA, none of Par's assertions specifically identify Athenex's compound vasopressin products. Athenex notes that Par alleged in its complaint that

an "undisclosed compounder" was preparing to launch "a bulk compounded vasopressin drug" (Doc. 17-11 ¶ 67), and that this "undisclosed compounder" was Athenex. (Doc. 16 at 14.) However, Par's indeterminate reference to the vasopressin products of an "undisclosed compounder" in a complaint alleging violations of the Administrative Procedure Act does not demonstrate specific intent to enforce the patents-in-suit against Athenex. *Cf. Glob. Tubing LLC v. Tenaris Coiled Tubes LLC*, No. 4:17-CV-3299, 2018 WL 3496739, at *4 (S.D. Tex. July 20, 2018) (finding actual controversy where patentee submitted document to the U.S. Patent and Trademark Office that not only stated "competitors are attempting to copy" its product but also specifically named the plaintiff).

Athenex also points to Par's public statements opposing bulk compounding of vasopressin and vowing to defend its products. (Doc. 1 ¶¶ 36, 38.) However, these general statements are irrelevant to whether Par intends to specifically enforce its patents against Athenex. *See Celltrion Healthcare Co. v. Kennedy Tr. for Rheumatology Research*, No. 14 CIV. 2256(PAC), 2014 WL 6765996, at *4 (S.D.N.Y. Dec. 1, 2014) ("[P]ublic statements regarding the patents owned by a patent owner, and that it defends the patent it owns, 'do not suffice to show an "imminent threat"' of litigation." (quoting *Sandoz Inc. v. Amgen Inc.*, No. C-13-2904 MMC, 2013 WL 6000069, at *2–3 (N.D. Cal. Nov. 12, 2013), *aff'd*, 773 F.3d 1274 (Fed. Cir. 2014))).

Athenex argues that "[b]ecause the patents-in-suit are listed in the Orange Book as covering Vasostrict®, it naturally follows that any products that are alleged to be copies of Vasostrict® by Par[] would also be . . . covered by Par's Orange Book-listed patents, and hence subject to a patent infringement suit by Par." (Doc. 16 at 11.) However, "[t]he existence of a patent, without more, does not create a case of actual controversy." *AIDS Healthcare Found.,*

*Inc.*, 890 F.3d at 991. Absent any evidence that Par has taken an affirmative action against Athenex, Athenex's speculative "fear of a future infringement suit is insufficient to confer jurisdiction." *Allied Mineral Prod., Inc. v. Osmi, Inc.*, 870 F.3d 1337, 1341 (Fed. Cir. 2017) (citing *Prasco*, 537 F.3d at 1338).

Considering the totality of the circumstances, the court concludes that Athenex has failed to allege that an actual controversy existed between the parties at the time the complaint was filed. Accordingly, this action must be dismissed for lack of subject matter jurisdiction.

**Conclusion**

Par's Motion to Dismiss (Doc. 10) is GRANTED.

Dated this 9 day of July, 2019.

Geoffrey W. Crawford, Judge
United States District Court